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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

7590 12/28/2009

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
12/28/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/060,849	MCALLISTER ET AL.	
	Examiner	Art Unit	
	S. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33,35,38-40,71-97,112-132 and 134-136* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The 112 rejections of record have been withdrawn in view of applicant's Remarks filed 09/04/09, at pages 23-27.

Claim Rejections - 35 USC § 103

Claims 1, 2, 7-16, 20-22, 39, 40, 73, 74, 81-74, 87-90, 92-95, 112 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189.

Petereit teaches an injection molding composition comprising: a) 45-100% methacrylate copolymer; b) 0.1-3% lubricant; c) 0-50% drier; d) 0-30% plasticizer; e) 0-100% additives or auxiliaries; f) active agent; and g) 0-20% of another polymer or copolymer (paragraphs 0019-0027). Methacrylate copolymer includes 50-70% methyl acrylate, 10-30% methyl methacrylate, and 5-15% methacrylic acid (a 7:3:1 ratio if converted) (paragraph 0038). Plasticizer includes castor oil, sorbitan ester, and polyethylene glycol (paragraphs 0050-0051). Other polymer or copolymer includes polyvinyl pyrrolidone (paragraphs 0078-0080). Petereit further teaches the shape of the molding includes capsule, part of a capsule such as half or a capsule (paragraph 0095). Petereit also teaches the wall thickness of the obtained capsule is of 0.6 mm (paragraph 0101).

Petereit does not explicitly teach the claimed percent amount of lubricant from 5% to about 30%. However, differences in concentration will not support the

patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In the present case, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select a lubricant amount that falls within the claimed range with the expectation of lat least similar result. This is because Petereit teaches the use of the same lubricant, such as stearyl alcohol, for the same purpose, namely, as a mold releasing agent (paragraphs 0041-0044). Further, the use of lubricant as a mold releasing agent in the claimed amount is known in the art. See for example the teaching of Lehmann at column 3, lines 65-67; and example 1. Lehmann teaches the use of 6% of the mold releasing agent, based on the weight of the polymer. Accordingly, it would have been obvious to one of ordinary skill in the art to modify the molding composition of Petereit using lubricant in the claimed amount in view of the teachings of Lehmann.

Petereit further does not teach that the capsule shell composition is substantially pH-independent. It is noted that nowhere in Petereit does the teaching of pH-dependent disclose. Accordingly, the burden is shifted to applicant to show that the capsule composition of Petereit is substantially pH-dependent. This is because Petereit teaches the use of the same polymers and in the same amounts to prepare a composition for the same purpose desired by the applicant, namely, a capsule shell composition useful in pharmaceutical art.

Claims 3-6, 18 and 75-80 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Bolles US 3,779,942 and Zentner US 4,795,644.

Petereit is relied upon for the reason stated above. Petereit does not expressly teach the use of surfactant.

Bolles teaches a capsule shell composition comprising well known polymer such hydroxypropyl cellulose, and surfactant such as sodium dioctyl sulfosuccinate in an amount of from about 0.001-10% (abstract; and column 2, lines 20-59). Thus, it would have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include surfactant to obtain the claimed invention. This is because Bolles teaches that the addition of surfactant to improve capsule shell storage stability, uniformity and strength (abstract; and column 2, lines 2-8).

Bolles does not teach the claimed surfactant such as sodium dodecyl sulfate. Zentner teaches useful surfactant for wall forming composition includes sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate (column 13, lines 53 through column 14, lines 1-22). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select sodium dodecyl sulfate as a surfactant, because Zentner teaches the equivalency between sodium dodecyl sulfate, and sodium dioctyl sulfosuccinate, and because Zentner teaches the use of sodium dodecyl sulfate in wall forming composition is known in the art.

Claims 1-33, 35, 38-40, 71-97, 112-132 and 134-136 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petereit et al. US 20020160042, in view of Lehmann et al. US 5,705,189, Hatano et al. US 6,309,666, and Klug et al. US 3,314,809.

Petereit is relied upon for the reasons stated above. Petereit further does not teach the inclusion of additives such as lactose and mannitol.

Hatano teaches coated capsule compositions comprising a hard outer shell (abstract). The compositions may be formulated for quick release at a desired location in the gastrointestinal tract (column 2, lines 49-62). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (column 5, line 42 to column 6, line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include mannitol, lactose and starch. Binders include ethylcellulose, polyvinylpyrrolidone, HPMC, and polyethylene glycol (column 12, lines 1-11). Disintegrants include polyvinylpyrrolidone and hydroxypropylcellulose (column 12, lines 12-17). Lubricants and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene sorbitan monooleate, poiyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (column 11, line 52 to column 12, line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (column 13, lines 3-5). Thus, it would

have been obvious to one of ordinary skill in the art to optimize the capsule shell composition of Petereit to include the excipients in view of the teachings of Hatano. This is because Hatano teaches the use of well known excipients in pharmaceutical art in capsule shell composition, and because Petereit teaches the desirability of using excipients or other auxiliaries known in the art.

It is noted that applicant argues that Petereit teaches the use of HPC in a long list, and there is no motivation to select HPC. However, Klug teaches a capsule shell composition comprising HPC (columns 1-2). Thus, the skilled artisan would have been motivated to select HPC as other polymer for the capsule shell composition of Petereit in view of the teachings of Klug, because Klug teaches that HPC is the stable thermoplastic material for making excellent articles such as capsule shell (column 4, lines 56 through column 5, lines 1-15).

Response to Arguments

Applicant's arguments filed 09/04/09 have been fully considered but they are not persuasive.

Applicant argues that the formulation of the copolymer blend used in the Petereit process does not teach a combination of two (2) dissolution modifying agents as required by claim 1 herein. One of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer. The copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend

does NOT require such an excipient to being present. The list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use within the context of Applicants invention as a dissolution modifying excipient. Therefore, even if a copolymer is present one would not necessarily be directed to pick and choose as an excipient that one which Applicant describes as a dissolution modifying excipient.

However, in response to applicant's argument that "*[o]ne of the dissolution modifying excipients for use in the instant invention is a swellable solid. In Petereit, there is no express statement of swellable solids, but use of a second copolymer*", it is noted that the "swellable solid" is recited in a Markush group. Thus, at least independent claim 1 does not necessarily require that the "swellable solid" as one of the dissolution modifying excipient in view of the Markush language. Further, in response to applicant's argument that "*the copolymer is an optional excipient in Petereit's blend, being present from 0-20% w/w. Consequently, the resulting blend does NOT require such an excipient to being present*", the Examiner notes that although the excipient is not required, it can be present. The phrase "optional" clearly indicates that it could be present. Moreover the amount of up to 20% indicates that the excipient does present in the blend.

Moreover, in response to applicant's argument that "*the list of polymers suitable for use in the Petereit formulation in disclosed in paragraph 0080 shown below. This paragraph provides for a long list of many polymers not claimed or disclosed for use*

within the context of Applicants invention as a dissolution modifying excipient", it is noted that the list of dissolution modifying excipients recited in claim 1 is broad. See for example "swellable solid" or "water soluble filler".

Applicant argues that in the present invention:

1) the capsule shell and/or linker is meant to break apart at a particular time, and release the contents of the shell/linker to the GI tract at that time, all at once, not over a period of time to provide a controlled constant rate of release;

2) the 4135F polymeric formulations provide for a capsule shell that has a more delayed, or prolonged time period to release the capsule contents into the GI tract; than a gelatin capsule which is of the immediate release;

3) when a multicomponent dosage form of the present invention, is assembled it is possible to have a shell subunit that disperses the contents as an immediate release, and be linked to a second, or third, etc. shell subunit that disperses the contents as pulsitile releases, much later down the GI tract; and

4) prior to the disclosure by Applicants it was not believed possible to prepare a pH-independent **capsule shell or linker itself** using the copolymers as recited in the presently amended claims.

However, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the captured features (1) to (4) above) are not recited at least in the rejected independent claim(s). Although the claims are interpreted in light of the

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

To place the application in condition for allowance, it is suggested to: 1) clarify the dissolution modifying excipients to include specific combination; and 2) incorporate the above captured features 1-4 into all independent claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615